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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,505	01/09/2006	Joerg Rosenberg	M/43212-US-1	4705

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EXAMINER	
KATAKAM, SUDHAKAR	

ART UNIT	PAPER NUMBER
1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,505	ROSENBERG ET AL.	
	Examiner	Art Unit	
	SUDHAKAR KATAKAM	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-31 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-31 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/10,6/29/10,10/4/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's remarks and arguments filed on 13 Dec 2010 is acknowledged.

2. In view of applicants' amendments to the claims, the previous rejection has been withdrawn, and however, a new ground(s) of rejection is made, since amendments changed the scope of the claims, given that different interpretation of the previously applied reference, newly found prior art and provides an explanation of the rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23-31 and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim subject matter which applicant regards as the invention.

The claim 23 recites calcium or quaternary ammonium salt of fenofibric acid. Calcium is a divalent, whereas quaternary ammonium is a monovalent and forms a monovalent salt. It appears that fenofibric acid is also a monovalent and forms a salt through its carboxylic acid group. It is not clear the how calcium forms a salt with monovalnet fenofibric acid. Clarification is requested.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

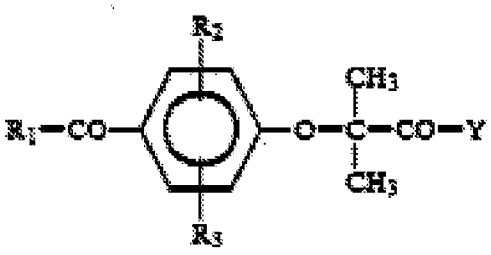
6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 23-31 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Boyer et al** (US 4,800,079) in view of **Bosca et al** (Photochemistry and Photobiology, 1999, 70(6), 853-857; see applicants filed IDS dated 8/27/2007), **Bastin et al** (Organic Process Research & Development, 2000, 4, 427-435; see applicants filed IDS dated 6/29/2010), **Berge et al** (J.Pharm.Salts, 1977, Vol.66, No.1, 1-19; see applicants filed IDS dated 6/29/2010) and **Kothrade et al** (US 6,284,803).

Determining the scope and contents of the prior art

Boyer teaches a medicine based on fenofibrate, and a method of preparing it. **Boyer** defined the term "fenofibrate and its derivatives" to designate a compound having the formula I, is represented by the following formula:



The above formula reads instant claim 1 when R_1 is phenyl group, R_2 and R_3 are hydrogen atoms, and Y is a -OH group [col. 1, lines 10-31]. **Boyer also** teaches various binders, selected from the group comprising methacrylic polymers, polyvinylpyrolidone, mixtures thereof; cellulose derivatives and polyethylene glycols [see claim 2].

Bosca et al teach the sodium salt of fenofibric acid [see Abstract and Results sections].

Bastin et al [see Table 1] and **Berge et al** [see Table 1] teach sodium, potassium, calcium, magnesium and zinc as common pharmaceutical salts and FDA approved commercially marketed salts.

Kothrade et al teach a pharmaceutical formulation [col. 14, line 45] in dosage form [col. 1, line 4] comprising fenofibrate as the active ingredient [col. 7, line 39], in the form of a molecular dispersion [col. 10, line 48], and a polymeric binder composed of methy/methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate [col. 5, lines 11-13, 20-21] and other conventionally acceptable excipients [col. 1, lines 4-7], which include flow regulators and silicates/silica gel [col. 6, lines 1 and 12]. The formulation is further obtainable by melt extrusion [col. 2, line 8; col. 5, line 35]. The formulation has a ratio of free carboxyl groups to esterified carboxyl groups around 1:1, based on the weight percentage of methyl methacrylate to acrylic acid [col. 2, lines 56-61] and the use of Eudragit types, which Applicant uses to exemplify this ratio preference [col. 5, line 12; col. 10, line 39] [see also specification page 7, lines 3-10]. The formulation

comprises 0.1 to 95%, preferably from 20 to 80%, in particular 30 to 70% by wei ght of the active substance [col. 6, lines 61-63], with ranges of 15-83% for the binder [col. 2, lines 19-45], in which the enteric binder (Eudragit types) is in the preferable range of up to 75% by weight of the binder component [col. 4, lines 65-67; col. 5, line 1 and 12] and with the range of up to 100%, in particular 0.02-50% of pharmaceutically/physiologically acceptable additives [col. 5, lines 66-67; col. 6, lines 7-8]. The preceding percentages would include a formulation in which the content of active substance component relative to binder is from 20 to 30% by weight.

Kothrade et al further teaches that all three components of the formulation: fenofibrate, binder component and other excipients/additives, can be combined [col. 1, lines 4-7; col. 7, lines 10-12 and 39].

With regard to claim 37, which describes a method for oral administration, since the dosage is in tablet form [col. 10, line 67], the expected mode of administration is oral administration. Additionally, applicant states that fenofibrate is usually administered orally [specification page 1, line 15].

With regard to claim 25 and 26, which describes the binder as an enteric binder/enteric polymer, because the art describes the polymeric binder• with the same components as applicant's, which include methyl methacrylate, acrylic acid, cellulose, acetate phthalate and hydroxypropylmethylcellulose phthalate [col. 5, lines 11-13, 20-21], therefore, the enteric property is inherent to the binder/polymer composition.

Ascertaining the differences between the prior art and the claims at issue

Boyer teaches fenofibric acid or its derivatives in medicinal compositions, but fails to teach applicants' calcium or quaternary ammonium salt of fenofibric acid.

Bosca et al teach the sodium salt of fenofibric acid, but fail to teach applicants' calcium or quaternary ammonium salt of fenofibric acid.

Bastin et al or **Berge et al** teach sodium, potassium, calcium, magnesium and zinc as common pharmaceutical salts, but fail to teach fenofibric acid in their disclosure.

Kothrade et al teach fenofibrate pharmaceutical formulations, but fail to teach calcium or quaternary ammonium salt of fenofibric acid.

Resolving the level of ordinary skill in the pertinent art

It appears the combination of teachings of above cited prior art read applicants' pharmaceutical composition.

Applicants' fenofibric acid is known in the art. Also art established sodium salt of fenofibric acid [**Bosca et al**]. Further art recognized or approved various cations, such as sodium, potassium, calcium, magnesium and zinc as common pharmaceutical salts [**Bastin et al** or **Berge et al**]. Therefore, all the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Considering objective evidence present in the application indicating obviousness or nonobviousness

The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, such as utilizing FDA approved pharmaceutical salts, and the invention resulted from application of the prior knowledge in a predictable manner.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teaching of the above cited references and to make instantly claimed pharmaceutical compositions with a reasonable expectation of success. Modifying such parameters is prima facie obvious because an ordinary artisan would be motivated to develop a new salts and their compositions from known or recommended salts so that to make the effective salt with superior properties for economical reasons or efficient purposes by using above cited reference teachings and to arrive applicants composition with a reasonable expectation of success, since it is within the scope to modify or combining the conditions through a routine experimentation.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 23-31 and 33-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims 1, 6 and 8-15 of US 7,259,186.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

They generically overlap. Instant claims are limited to calcium or quaternary ammonium salt of fenofibric acid, whereas the claims of US patent encompasses choline, ethanolamine, diethanolamine, piperazine, calcium, and tromethamine. Therefore, the claims differ in the scope of the claimed cationic compounds for the salt.

It would have been a prima facie obvious to a person of ordinary skill in the art, at the time the present invention was made, to utilize the compounds from US patent and to expect the instant claims with a reasonable expectation of success. The difference, however, does not constitute a patentable distinct, because the claims in the present invention simply fall with in the scope of US patent, since the similar components in the composition. Hence the instant claims overlap with the claims of the US patent.

Response to Arguments

10. Applicant's arguments filed on 13 Dec 2010 have been fully considered but they are not persuasive.

Applicants' arguments are moot, in view of above new grounds of rejection.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Primary Examiner, Art Unit 1621